

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW	:	
PRODUCTS LIABILITY LITIGATION	:	
_____	:	
	:	
THIS DOCUMENT RELATES TO ALL ACTIONS	:	MDL DOCKET NO. 1014
_____	:	
	:	
DANIEL FANNING et al.	:	
	:	
and	:	
	:	
MARGARET SCHMERLING et al.	:	
	:	
v.	:	C.A. No. 97-381
	:	
ACROMED CORPORATION	:	
_____	:	

PRETRIAL ORDER NO. 1117

FINAL ORDER AND JUDGMENT

AND NOW, TO WIT, this 17th day of October, 1997, upon consideration of the Joint Motion of the Plaintiffs' Legal Committee ("PLC") and AcroMed Corporation ("AcroMed") for Approval of the Proposed Settlement Agreement and for Certification of a Settlement Class under Rule 23(b)(1)(B) IT IS ORDERED that:

1. The capitalized terms used in this Final Order and Judgment shall have the same meaning as those in the Agreement, as amended except for the following clarifications that have been agreed to by AcroMed and the PLC:

a. The Agreement includes AcroMed's insurers within the definition of "AcroMed." No insurer will be released

until the efforts of AcroMed and the PLC to obtain that insurer's contributions to the AcroMed Settlement Fund are completed to the satisfaction of AcroMed, the PLC, and the court.

A. The Settlement Class

1. The Settlement Class IS CERTIFIED, FOR SETTLEMENT PURPOSES ONLY, under Fed. R. Civ. P. 23(a), 23(b)(1), and 23(e) in Fanning, et al. v. AcroMed Corporation (the "Action") and is defined as follows:

All persons and entities wherever located, who have or may in the future have any claim (whether filed or unfiled, existing or contingent, and specifically including claims for alleged injuries and damages not yet known or manifest), including assigned claims (e.g. subrogation claims by workers' compensation insurers, employers, and/or health care insurers or providers), in any state or federal courts of the United States or the courts of its territories or possessions, against any or all of AcroMed and the Released Parties arising out of, based upon, related to, or involving Orthopedic Bone Screws that were implanted in the United States or its territories or possessions in an operation that occurred on or before December 31, 1996, including all persons who have been implanted with one or more Orthopedic Bone Screws on or before December 31, 1996 (whether or not any such Orthopedic Bone Screw has been or may be removed) and all persons, including spouses, parents, children, relatives, "significant others" where warranted by law, representatives, and estates, that, because of a personal relationship with any Orthopedic Bone Screw Recipient in whom an Orthopedic Bone Screw was implanted on or before December 31, 1996, have or may have Orthopedic Bone Screw Related claims.

The Settlement Class does not include (a) AcroMed, the Released Parties, the Professional Societies, or any person claiming by or through such persons and entities or (b) any Non-Settling Defendant, including without limitation, all device manufacturers or health care providers named as defendants in MDL Docket No. 1014, or any person claiming by or through such persons or entities, except to the extent that the Non-Settling Defendant is an insurance carrier that, in some other capacity, may assert assigned claims or subrogation rights, in which case the insurance company is a settlement class member only for purposes of asserting assigned claims or subrogation rights.

2. The court's findings are without prejudice to AcroMed's rights under Fed. R. Civ. P. 23 and the Agreement if the Settlement is not finally approved at the expiration of all appeal periods.

B. The Fairness of the Settlement

1. The Agreement and the amendments to the Agreement have been entered into in good faith following arms-length negotiations and are non-collusive. The proposed Settlement of the Action on the terms and conditions set forth in the Agreement, as amended, is fair, reasonable, adequate, and in the best interest of the Settlement Class. The Settlement is also fair, reasonable, and adequate from the perspective of Non-Settling Defendants and other affected parties.

2. The Notice provided for and given to the Settlement Class constitutes the best notice practicable under the circumstances and fully complies with the notice requirements of due process and Fed. R. Civ. P. 23.

C. The Settlement Terms

1. The Agreement, as amended, and the proposed Settlement are hereby APPROVED and shall be consummated in accordance with the terms and provisions of the Agreement, as amended.

2. The Action is DISMISSED WITH PREJUDICE and without costs to any party, in accordance with Fed. R. Civ. P. 23. AcroMed and the Released Parties are hereby released and discharged, as to each and every Settlement Class Member, from any and all claims, actions, causes of action, rights, and liabilities whatsoever, known or unknown, in any capacity in any court or tribunal, for any relief, alleged or asserted or that could have been alleged or asserted in the Action, or based upon, relating to, or connected in any way to, or arising out of any of the acts, failures to act, representations, omissions, matters, actions, transactions, agreements, situations, courses of conduct, facts, or circumstances alleged or referred to in the Action.

3. All actions pending in MDL Docket No. 1014 involving AcroMed Orthopedic Bone Screws and/or AcroMed Orthopedic Bone Screw Recipients are STAYED until further Order of the court as to all persons other than AcroMed, the Released Parties, and the Professional Societies. All actions are DISMISSED WITH PREJUDICE as to AcroMed, the Released Parties, and the Professional Societies, on the merits and without costs to any party. All actions pending in MDL Docket No. 1014 involving Non-AcroMed Orthopedic Bone Screws and/or Non-AcroMed Orthopedic Bone Screw

Recipients are DISMISSED WITH PREJUDICE as to AcroMed and the Released Parties on the merits and without costs to any party. The stay of actions involving AcroMed Orthopedic Bone Screws and/or AcroMed Orthopedic Bone Screw Recipients as to medical device manufacturers other than AcroMed named as defendants in those cases shall be lifted only (a) as to a particular person in connection with a settlement in MDL Docket No. 1014 between the PLC and that person in which the PLC complies with the terms of the Agreement or (b) under terms and conditions (including but not limited to appropriate funding of the AcroMed Settlement Contingency Fund), proposed by the PLC and/or AcroMed, accepted by AcroMed (which acceptance shall not be unreasonably withheld), and approved by the Court, sufficient to protect AcroMed's interest in the finality of the Settlement and this Order and AcroMed's rights under the Agreement.

4. All Settlement Class Members are permanently BARRED and ENJOINED from initiating, asserting, or prosecuting any Orthopedic Bone Screw related actions against AcroMed or the Released Parties.

5. All Settlement Class Members who are AcroMed Orthopedic Bone Screw Recipients (or whose claims rest on the implantation of AcroMed Orthopedic Bone Screws) are ENJOINED, until further Order of the Court, from initiating, asserting, or prosecuting any actions presenting claims in the nature of conspiracy or concert of action against any person other than AcroMed, the Released Parties, and the Professional Societies. This

injunction shall be lifted only (a) as to a particular person in connection with a settlement in MDL Docket No. 1014 between the PLC and that person in which the PLC complies with the terms of the Agreement or (b) under terms and conditions (including but not limited to appropriate funding of the AcroMed Settlement Contingency Fund), proposed by the PLC and/or AcroMed, accepted by AcroMed (which acceptance shall not be unreasonably withheld), and approved by the Court, sufficient to protect AcroMed's interest in the finality of the Settlement and this Order and AcroMed's rights under the Agreement.

6. All Settlement Class Members who are AcroMed Orthopedic Bone Screw Recipients (or whose claims rest on the implantation of AcroMed Orthopedic Bone Screws) are permanently BARRED and ENJOINED from initiating, asserting, or prosecuting any actions presenting Settled Claims against any party. Settlement Class Members who are AcroMed Orthopedic Bone Screw Recipients (or whose claims rest on the implantation of AcroMed Orthopedic Bone Screws) may not initiate, assert, or prosecute Orthopedic Bone Screw related claims, unless: (a) the claim is in the nature of a claim for alleged independent medical malpractice against any physician who treated the Settlement Class Member or any institution at which the Settlement Class Member was treated based upon medical care rendered to the Settlement Class Member; and (b) the claim does not (I) rest in whole or in part on any product liability-related theory of recovery, including without limitation design or manufacturing defect, the regulatory status

of any AcroMed Orthopedic Bone Screw, or alleged failure to warn, nondisclosure, or inaccurate or incomplete disclosure, of the regulatory status of any AcroMed Orthopedic Bone Screw or (ii) have as an element of the claim financial relationships with AcroMed and/or an alleged conflict of interest based upon any such financial relationship (impeachment shall not be considered an element of a claim).

7. AcroMed and the Released Parties are RELEASED and DISCHARGED from all Settled Claims of all Settlement Class Members. The Professional Societies are RELEASED and DISCHARGED from all Settled Claims of all Settlement Class Members who are AcroMed Orthopedic Bone Screw Recipients (or whose claims rest on the implantation of AcroMed Orthopedic Bone Screws).

8. Each Settlement Class Member shall be deemed to have relinquished, to the fullest extent permitted by law, the provision, rights, and benefits of any state or federal law, rule, or regulation that purports to restrict the scope of a general release to claims which the party knows or suspects to exist in his favor, whether or not knowledge of such a claim would have materially affected his settlement with the other party.

9. Non-Settling Defendants and other third parties are permanently BARRED and ENJOINED from initiating, asserting, or prosecuting any claim or action, including Claims for Contribution, Indemnity, and/or Subrogation, against AcroMed and the Released Parties for reimbursement of payments made to or on

behalf of any Settlement Class Member for Orthopedic Bone Screw related claims or injuries, subject only to the following exception:

a. If, despite the provisions of Section XI.B.1 of the Agreement, (I) applicable law precludes a Non-Settling Defendant from obtaining a set-off or judgment reduction to which a Non-Settling Defendant would otherwise be entitled under applicable law in an individual case brought by a Settlement Class Member without naming AcroMed or a Released Party as a party in the lawsuit and (ii) the Non-Settling Defendant and the Settlement Class Member cannot reach agreement on this issue sufficient to eliminate the Non-Settling Defendant's alleged need to name AcroMed or a Released Party in the lawsuit, the Non-Settling Defendant may apply to the Court for relief from this bar order.

b. The Non-Settling Defendant's application to the Court shall set forth with specificity (I) the facts and law that would give rise to a claim for contribution or indemnity but for the provisions of this Agreement; (ii) the efforts that the Non-Settling Defendant has made to reach an accommodation with the Settlement Class Member with respect to the need to name AcroMed or a Released Party as a defendant in the case; and (iii) the factual and legal bases for the Non-Settling Defendant's claim that, under the particular facts of the case and the particular provisions of applicable law, the Non-Settling Defendant must be permitted to name AcroMed or a Released Party in the case despite the bar order.

c. A copy of the Non-Settling Defendant's application to the Court shall be served on the PLC and counsel for AcroMed.

d. The Court shall modify the bar order to permit a Non-Settling Defendant to name AcroMed or a Released Party in a particular case brought against the Non-Settling Defendant by a Settlement Class

Member only where doing so is essential to protect set-off or judgment reduction rights to which the Non-Settling Defendant would be entitled under applicable law but for the provisions of this Agreement. Any order modifying the bar order will contain provisions that protect the interests of AcroMed and the Released Parties under this Agreement, including, among other things, provisions affirming that the Settlement Class Member has agreed (I) to forego any direct or indirect recovery from AcroMed or the Released Parties of sums over and above those received under this Agreement and (ii) to give up any portion of any judgment obtained against a Non-Settling Defendant that is attributed to AcroMed or any Released Party.

e. Applications made by Non-Settling Defendants for modification of the bar order will be subject to the provisions of Fed. R. Civ. P. 11.

10. Decisions regarding the timeliness and validity of claims by which persons claiming subrogation rights seek to recover from the AcroMed Settlement Fund are reserved for initial consideration by the Claims Administrator, subject to later review by this Court.

11. The Agreement, this Final Order and Judgment, and all papers related to the Settlement are not, and shall not in any event be, an admission by AcroMed, the Released Parties, or any other person of any liability or wrongdoing whatsoever, and shall not be offered as evidence of any claimed liability or wrongdoing whatsoever in this or any future proceeding.

12. The Court approves the termination provisions of Section VII of the Agreement so that, if the Agreement is terminated, all monies paid by AcroMed, plus all interest

actually earned or accrued, less any Notice Expenses and Administrator Expenses, shall be returned to AcroMed.

13. The Parties are directed to carry out their obligations under the Agreement forthwith.

14. This Court reserves continuing and exclusive jurisdiction over the Parties to the Agreement, including AcroMed and the Released Parties, and all Settlement Class Members, to administer, supervise, construe, and enforce the Agreement and this Final Order and Judgment in accordance with their terms for the mutual benefit of the Parties and the Settlement Class. The Court retains continuing and exclusive jurisdiction for purposes of, among other things, approval of the Condition Definitions and Compensation Schedule, supervision and administration of the Compensation Program, the payment of attorneys' fees and expenses and awards to Settlement Class Members, and matters concerning claims administration and the distribution of settlement funds and payment of related fees and expenses until the effectuation of the Settlement in accordance with the Agreement has been accomplished.

15. This Order is binding on ALL Settlement Class Members.

16. The Clerk of Court is directed to enter this Final Order and Judgment as a final judgment under Fed. R. Civ. P. 54(b).

LOUIS C. BECHTLE, J.